Domtar

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Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Proposed Regulations for Prior Notice of Imported Food
FDA Docket No. 02N-0278

Dear Sir or Madam:

I am writing on behalf of Domtar Inc. to provide comment on the proposed FDA regulations resulting from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Domtar is North America's third largest producer of uncoated freesheet paper and a major producer of specialty paper products. We have manufacturing facilities in both the United States and Canada and employ more than 12,500 employees who contribute to an annual sales revenue of approximately $2.748 billion (U.S. dollars). Domtar Inc. also manufactures wood products and market pulp. We produce approximately 380,000 tons annually of technical and specialty paper products and about 2.78 million tons of paper products overall each year. Many of our specialty paper products are designed for and employed in direct food contact end uses and are manufactured to be compliant with long standing FDA regulations.

Domtar Inc., as a member company of the American Forest and Paper Association (AF&PA) supports the AF&PA position on the proposed FDA regulations.

1. FDA's Proposed Inclusion of Food Packaging and Other Food Contact Substances in the Definition of "Article of Food" is Not Consistent with Congressional Intent
2. Inclusion of Food Packaging and Other Food Contact Materials is Not Consistent with FDA's Food Security Preventive Measures Guidance
3. Subjecting Food Packaging and Food Contact Substances and Articles to Prior Notice Will Not Further the Purposes of the Bioterrorism Act
4. Separate Notification for Food Packaging and Food Contact Articles is Duplicative
5. FDA Underestimates the Burden of the Proposed Regulation

I would like to provide additional comments on behalf of Domtar Inc.

- The prior notification requirements are overly burdensome and complex.
- The proposed FDA requirement for prior notification will cripple the operations of border crossings and ports of entry. The proposed language will have an unintended effect of creating massive border crossing back-ups of truck traffic. Presently, key border crossings from Canada into Michigan routinely have a two to five hour truck back-up. This delay alone will render the timing of prior notification problematic. Couple that with the resulting rejection of shipments, we anticipate trucking will come to a virtual stand still at key border crossings. That will have a secondary effect of creating a general shortage of trucks available in which to conduct cross-border commerce of all types. We have already seen such shortages of trucks, as well as more significant border crossing delays in the weeks following September 11th. The proposed prior notification regulations will ensure such problems are institutionalized.

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- NAFTA created a significant regionalized manufacturing boom in and around border crossings. This enabled just-in-time shipments to transcend national borders in North America for the benefit of commerce internationally. The prior notification regulations as proposed by FDA will significantly negate the negotiated advantages to all NAFTA member countries. The just-in-time advantages for businesses straddling the border will vanish given the anticipated degree of difficulty and delay in making the cross-border shipments.
- The proposed regulations are a duplication of regulatory effort. FDA has already promulgated regulations that require food contact packaging to be "unadulterated" and contain "no poisonous or deleterious substances".
- The proposed regulations will create a secondary and unintended landslide of customer requests to document that we are in compliance with the proposed FDA regulations. These requests, while not specifically part of the proposed legislation, will occur as our well intended customers scurry to insure the continued safety of the products they buy. We will feel a need to also request similar documentation from our suppliers of components used to manufacture food contact paper products. This will result in a significant burden and we anticipate additional employees will need to be hired simply to deal with this administrative burden, which will yield no additional safety to the food supply of the United States.
- For companies that ultimately fall under the proposed FDA regulations, we suggest that the agency look at the CT-PAT (Customs and Trade in Partnership Against Terrorism) model, currently being implemented by the Department of Homeland Security's Bureau of Customs and Border Protection. We suggest that the FDA coordinate with the Bureau of Customs and Border Protection to eliminate duplicative reporting for those companies participating in CT-PAT, as well as programs administered by the FDA.

FDA should, as AF&PA suggests and Domtar Inc. supports, replace its erroneous definition of "food" with an accurate definition of "article of food" for purposes of the prior notice requirement to exclude food packaging and other food contact articles not in contact with food at the time of import. Doing so is consistent with the statute, the legislative history, and the congressional intent, as well as FDA's mission to protect the safety of the United States food supply under the Bioterrorism Act of 2002.

Respectfully submitted,

Howard L. Hunter
Manager, New Product Development
Technical and Specialty Papers
Domtar Representative on the
AF&PA Food Packaging Safety Subcommittee

Thomas S. Howard
Director of U.S. Government Relations